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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,882	12/19/2001	Sheldon Tobe	PT-1949001	8815

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,882	TOBE, SHELDON	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *2-8,11-13,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,10,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/16/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant is advised that this application has been transferred to Technology Center 1600 and this Examiner in Art Unit 1616 based on the restriction requirement of 7/13/2004 and applicant election of 8/10/2004.

Claims 1-17 are pending in this application.

Applicant's election with traverse of the invention of Group I, claims 1, 9, 10, 14 and 17, in the reply filed on 8/10/2004 is acknowledged. The traversal is an incorporation of applicant's response of 4/8/2004. This traversal was fully addressed by the previous Examiner in the second restriction requirement, which was mailed on 7/13/2004. Applicant also states that "it makes little sense to group dependent claims apart from their corresponding independent inventions." This is not found persuasive, because a restriction into several inventions is not precluded by the fact that various dependent claims (directed to distinct inventions) ultimately refer back to the same independent claim. If this were not the case, a little bit of creative claim drafting would void any and all future restriction requirements. The test for the propriety of a restriction has always been the dual test of independence/distinctness and undue burden. Having met both of these requirements, as fully set forth by the previous Examiner in the two previous restriction requirement Office actions, the requirement is still deemed proper and is therefore made FINAL.

Claims 2-8, 11-13 and 15-16 are withdrawn from further consideration as being directed to non-elected subject matter. Claims 1, 9-10, 14 and 17 will presently be examined.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Even though claims 1 and 10, standing alone without each other, appear to be specific and clear, when they are reviewed in view of each other, they are confusing and indefinite. Claim 1 requires a specific amount of three ingredients and claim 10 requires a specific amount of four components upon dilution of the concentrate of claim 1. However, when one calculates the resulting concentrations of magnesium from the concentrate of claim 1, something appears amiss.

Concentrate of claim 1	Use concentration of solutes in claim 10
90.72 g/l of NaCl = 1.55 moles/l	Na 140±14 mmol/l
2.05 g/l of $MgCl_2$ = 0.0215 moles/l	Mg 0.75 ± 0.07 mmol/l
28.35 g/l of $NaHCO_3$ = 0.337 moles/l	Cl 116.5 ± 11 mmol/l
	HCO_3 25 ± 2.5 mmol/l

From the above figures, it can be seen that in order to arrive at the diluted concentrations of three of the components, Na, Cl and HCO_3, the concentrate of claim 1 would have to be diluted about 13.5-fold (taking into consideration that Na comes from both NaCl and $NaHCO_3$ and Cl comes from both NaCl and doubly from $MgCl_2$).

However, for Mg alone the dilution has to be about 28.6-fold for the numbers to work out right. Therefore, something is not right here. The dialysis concentrate of claim 1, as presently claimed, cannot be diluted one way for Na, Cl, HCO_3, and another way for Mg. Either the dialysis concentrate in claim 1 is requiring an incorrect weight amount for $MgCl_2$ or the diluted solution in claim 10 is requiring an incorrect concentration for magnesium.

If applicant intends to correct this error, applicant is forewarned as to new matter issues. At this time, it is not clearly conveyed from the original disclosure which way the error lies – is the error in the weight amount of $MgCl_2$ given in claim 1 or the concentration of Mg given in claim 10? Sufficient basis must be shown to establish that applicant's amendment does not add new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Mahiout (US 6,492,336).

Mahiout explicitly discloses a peritoneal dialysis solution that contains the following anions and cations (see claim 18 in view of claim 1):

125-140 mEq/l of sodium;

90-125 mEq/l of chloride;

1-5 mEq/l calcium;

0.2-5 mEq/l of magnesium; and

25-40 mEq/l of a buffering anion selected from the group consisting of lactate, pyruvate and bicarbonate.

Sterilization of the solution and use of sterile, pyrogen free water are explicitly taught (column 8, lines 43-51; column 10, lines 42-54).

Applicant's claim 9 requires a physiologically acceptable diluent. Mahiout's sterile, pyrogen free water meets this claim feature. Applicant's claim 10 recites specific concentration ranges for sodium, magnesium, chloride, and bicarbonate. Magnesium at 0.75 ± 0.007 mmol/l is the same as about 1.5 mEq/l, which is squarely within Mahiout's concentration range. All other solutes claimed by applicant are also squarely within Mahiout's concentration range. The claims are thereby anticipated.

Claims 14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chemical Abstract 124:325351.

Chemical Abstract 124:325351 explicitly discloses treating advanced renal failure patients with a calcium-free dialysis solution, which contains the following solutes:

135 mmol/l of sodium;

0.75 mmol/l of magnesium;

108 mmol/l of chloride;

30 mmol/l of bicarbonate;

2.5 mmol/l of potassium.

Even though the cited reference does not expressly state that the calcium-free dialysis solution is "sterile," such a feature would necessarily have been present due to the fact that a dialysis solution that is not sterile would have grave consequences for patients with advanced renal failure. The claim language of applicant's claims 14 and 17 with respect to minimizing risk of metabolic complications is noted, but it is the Examiner's position that the dialysis solution specifically disclosed by the cited reference is exactly within the metes and bounds of applicant's dialysate component requirements, and any such metabolic complication minimization would have been an inherent property of the specific calcium-free dialysis solution expressly disclosed by the cited reference. See MPEP 2112, 2112.01. The claims are thereby anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chemical Abstracts 124:332435 in view of Mahiout.

Teachings of the Chemical Abstracts reference were fully discussed above in the preceding ground of rejection and the discussion there is incorporated herein by reference to avoid repetition.

Mahiout is cited to establish that using a sterilized dialysis solution is common practice in this field (column 8, lines 43-51; column 10, lines 42-54; column 11, lines 22-23, 31-32, 41-42, 51-52, 62-63).

In this alternative ground of rejection, it is noted that the cited Chemical Abstracts reference does not state in verbatim language that the dialysis solution there is "sterile." However, one having ordinary skill in the art would have been motivated to sterilize the dialysis solution taught by Chemical Abstracts 124:332435 if it wasn't already sterile, because doing so would have provided a benefit to the already seriously ill patients with advanced renal failure.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of

the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

It is noted that this application is related to a published PCT application, WO 2002049693 and published Canadian application, CA 2365787. If applicant has received a search report or notification of relevant prior art, written opinion or IPER in such applications, submission of such information would aid in the examination of this application.

Lastly, applicant is queried whether the commercial product, "NORMOCARB" is in any way related to this application, claimed invention, or the assignee of this application. Applicant is advised that this is not yet a formal Request for Information under Rule 105 because the Examiner does not yet have sufficient basis to determine whether the information is "reasonably necessary" to determine the issues in this application. The Examiner believes NORMOCARB to be a bicarbonate based dialysate solution but does not yet have additional information on the product.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600